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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,894	07/14/2003	Gilad Lavi	E1067/20278	7357

31717 7590 01/24/2006

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EXAMINER

HUH, BENJAMIN

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Sp

Office Action Summary	Application No.	Applicant(s)	
	10/618,894	LAVI ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/14/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 & 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6645181 in view of Stein (US Patent No. 3677246). Claim 2 of Patent No. 6645181 discloses all of the components of claim 1 of application 10/618894 except that the "pressurizing mechanism that pressurizes the container to move the fluid" does not consist of a "compression means for manually pressurizing the drug in the standard container". Even though the patent '181 does not claim the "manual compression means" attention is directed to Stein. Stein discloses an "injector" which has a manual compression

means for pressurizing the drug in the standard container as seen in figure 1 also see col. 2 lines 24-20. Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the "manual compression means" of Stein into the patent '181 reference in order to be able to better control the amount of compression the vial is placed under as well as to regulate the amount of drug flowing out of the container.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

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Information Disclosure Statement

It is acknowledged that the applicant has not submitted an Information Disclosure Statement as of 1/11/2006.

Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, mean-plus-function language to define Applicant's invention in claim 1. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the

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structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) ...". (Also see MPEP 2181 (Rev. 1, Feb. 2000))

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Stein (US Patent No. 3677246). Stein discloses a method of drug delivery comprising providing a housing 1 having a first port 12 that receives a standard container 3 of fluid along a first axis; manually pressurizing the fluid in the standard container 3 (see col. 2 lines 15-40); and manually moving an injection penetrating member 2f from a storage position to an injection position along a second axis, the injection penetrating member 2f being in fluid communication with the standard container 3 as seen in figure 1. Note that it is not stated that the first and second axis can not be parallel nor coaxial the first and second axis can be parallel or coaxial.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 10-12, 14, & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US Patent No. 5814020) in view of Shaw (US Patent No. 5389076). Gross discloses a device for injecting a fluid into a living being comprising a housing 10 having a penetrating member aperture having a first longitudinal axis in figure 2, a port 20 in said housing that receives a standard rigid container 19 which is seen as a rigid container that is standard for the device of figure 2 and would be standard since it is known prior art that contains a drug 24, said port 20 having a second longitudinal axis; compression means for manually pressurizing the drug in the standard container (see col. 8 lines 20-34); a gas impermeable sealing member 18; a penetrating member 14 moveable from a storage position seen in figure 2 in the housing to an injection position seen in figure 4 extending outside the housing through the aperture; a channel (22, 23, 12) that is part of a manifold in figure 2, that brings said penetrating member into fluid communication with the container, which comprises a second channel 13 to transfer the drug from the housing to the living being; wherein the first longitudinal axis and second longitudinal axis are not parallel nor coaxial. Even though Gross does not disclose a penetrating member retraction mechanism for retracting said penetrating member into said housing after delivering the

drug attention is directed to Shaw. Shaw discloses a "device for injecting a fluid into a living being" which discloses a penetrating member retraction mechanism for retracting said penetrating member into said housing after delivering the drug see figures 1-5, therefore it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the "retracting mechanism" of Shaw to the device of Gross in order to prevent the user or another from injury due to the needle. It is commonly known for injectors to have retracting mechanisms in order to prevent the risk of infection or injury to the user, medical personnel, sanitation employees and others who could come in contact with the device.

With regards to claim 3 & 14, the reference further comprises an actuator 27 that displaces the penetrating member 14 from the storage position to an injection position (see col 9. lines 5-15).

With regards to claim 4, where a plunger is defined as "a mechanical device that has a plunging or thrusting motion" wherein the actuator 27 includes a plunger mechanism on a first housing surface that displaces said member through the aperture on a second housing surface between the storage position and the injection position (see col 9. lines 5-15) wherein the thrusting motion of the device would cause this action.

With regards to claim 10, the penetrating member is moveable from a storage position to an injection position by manual operation (see col. 9 lines 5-15).

With regards to claim 15, the Gross reference clearly shows a method of providing a housing 10 having a first port 20 that receives a standard container 19 of

fluid 24 along a first axis; manually pressurizing the fluid in the standard container (see col. 8 lines 20-34); and manually moving an injection penetrating member from a storage position to an injection position along a second axis, the injection penetrating member being in fluid communication with the standard container as can be seen in figures 2 & 4.

Claims 8 & 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US Patent No. 5814020) in view of Shaw (US Patent No. 5389076) in further view of Dwyer (US Patent No. 3605744). Even though Gross does not disclose the penetrating member to extend in the range of 5-12 mm out of the housing in an injection position or to extend up to about 3 cm out of said housing in an injection position attention is directed to Dwyer. Dwyer discloses a device for adjusting the needle relative to the injector housing in order to obtain the depth of injection desired. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Gross in view of Shaw with the depth adjustment components of Dwyer in order to inject the needle to the desired location in order to be able to deliver the drug to the necessary location.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Other references with retraction mechanisms are Levin et al

(Patent No. 4787891), Stradella (US Patent No. 6099503), & Wyrick (US Patent No. 5665071). Another reference that discloses the depth adjustment for an injection is Hjertman et al (US Patent No. 5873856).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BHH



MICHAEL J. HAYES
PRIMARY EXAMINER